Paclitaxel trials will be selected for the Phase II component. The number will be based on the desire to establish tumor response rate with acceptable precision at the 95% confidence level. As such, the study will be single armed with the goal of establishing equivalence with standard Paclitaxel by showing that the confidence interval contains the expected response rates for Capxol™. The patient sample size used will be 30 patients, which is common for the Phase II component of a Phase I/II study.

Measurement: The primary outcome will be the tumor response rate (CR/PR) for the enrolled patients. In addition, the time to response, duration of response, and survival time will be monitored. Safety of the treatment will also be evaluated from adverse event rates and changes in standard laboratory parameters.

That which is claimed is:

1. A method for reducing the toxicity of paclitaxel in a subject undergoing treatment with paclitaxel, said method comprising systemically administering said paclitaxel to said subject in a pharmaceutically acceptable formulation at a dose of at least 175 mg/m^2 over an administration period of no greater than 2 hours.

2. A method according to claim 1, wherein said dose is at least 250 mg/m^2.

3. A method according to claim 1, wherein said dose is at least 325 mg/m^2.

4. A method according to claim 1, wherein said administration period is no greater than 1 hour.

5. A method according to claim 1, wherein said administration period is no greater than 30 minutes.

6. A method according to claim 1, wherein said paclitaxel is administered orally, intramuscularly, intravenously, intraperitoneally, or by inhalation.

7. A method according to claim 1, wherein said treatment is for prostate cancer, orchidectomy, pancreatic cancer, or brain tumor.

8. A method according to claim 1, wherein the hematologic or neurological toxicity of said paclitaxel is reduced.

9. A method for the administration of paclitaxel to a subject in need thereof, without the need for pre-medication prior to administration of said paclitaxel, said method comprising systemically administering said paclitaxel to said subject in a pharmaceutically acceptable formulation at a dose of at least 135 mg/m^2 over an administration period of no greater than 2 hours.

10. A method according to claim 9, wherein said dose is at least 250 mg/m^2.

11. A method according to claim 9, wherein said dose is at least 325 mg/m^2.

12. A method according to claim 9, wherein said administration period is no greater than 1 hour.

13. A method according to claim 9, wherein said administration period is no greater than 5 minutes.

14. A method according to claim 9, wherein said paclitaxel is administered orally, intramuscularly, intravenously, or intraperitoneally, intraarterial, intraurethral, intrathecal.

15. A method according to claim 9, wherein said treatment is for prostate cancer, orchidectomy, pancreatic cancer, or brain tumor.

16. A method for the administration of paclitaxel to a subject in need thereof, said method comprising systemically administering said paclitaxel to said subject in a pharmaceutically acceptable formulation at a dose of at least 135 mg/m^2 over an administration period of no greater than 2 hours, with a treatment cycle of less than 3 weeks.

17. A method according to claim 16, wherein said dose is at least 250 mg/m^2.

18. A method according to claim 16, wherein said dose is at least 325 mg/m^2.

19. A method according to claim 16, wherein said treatment cycle is less than 2 weeks.

20. A method according to claim 16, wherein said treatment cycle is less than 1 week.

21. A method according to claim 16, wherein said paclitaxel is administered orally, intramuscularly, intravenously, or intraperitoneally.

22. A method according to claim 16, wherein said treatment is for prostate cancer, orchidectomy, pancreatic cancer, or brain tumor.

23. A method for the administration of paclitaxel to a subject in need thereof, said method comprising systemically administering said paclitaxel to said subject in a pharmaceutically acceptable formulation at a dose of at least 250 mg/m^2.

24. A method according to claim 23, wherein said dose is at least 325 mg/m^2.

25. A method according to claim 23, wherein said treatment cycle is less than 2 weeks.

26. A method according to claim 23, wherein said treatment cycle is less than 1 week.

27. A method according to claim 23, wherein said paclitaxel is administered orally, intramuscularly, intravenously, or intraperitoneally.

28. A method according to claim 23, wherein said treatment is for prostate cancer, orchidectomy, pancreatic cancer, or brain tumor.

29. A method for the administration of paclitaxel to a subject in need thereof, said method comprising systemically administering said paclitaxel to said subject in a formulation that may be safely administered using medical hardware made from materials containing extractable components.

30. A method according to claim 29, wherein said medical hardware is selected from the group consisting of tubing, catheters, infusion bags, bottles, and syringes.

31. A method for the administration of paclitaxel to a subject in need thereof, said method comprising systemically administering said paclitaxel to said subject in a formulation that may be safely administered without the use of an in-line filter.

32. A method for the administration of paclitaxel to a subject in need thereof, said method comprising systemically administering a complete dose of said paclitaxel to said subject in a volume of less than 250 ml.

33. A method according to claim 32, wherein said volume is less than 150 ml.

34. A method according to claim 32, wherein said volume is less than 60 ml.

35. A method for the administration of paclitaxel to a subject in need thereof, said method comprising systemically administering said paclitaxel to said subject at a rate of at least 50 mg/m^2/hour.

36. A formulation of paclitaxel having reduced hematologic toxicity to a subject undergoing treatment with paclitaxel, said formulation comprising paclitaxel in a pharmaceutically acceptable formulation suitable for systemic administration at a dose of at least 175 mg/m^2 over an administration period of no greater than 2 hours.

37. A formulation according to claim 36 wherein said dose is at least 250 mg/m^2.

38. A formulation according to claim 36 wherein said dose is at least 325 mg/m^2.

39. A formulation of paclitaxel suitable for administration of paclitaxel to a subject in need thereof, without the need for pre-medication prior to administration of said paclitaxel, said formulation comprising paclitaxel in a pharmaceutically acceptable formulation suitable for systemic administration at a dose of at least 135 mg/m^2 over an administration period of no greater than 2 hours.

40. A formulation according to claim 39 wherein said dose is at least 250 mg/m^2.

41. A formulation according to claim 39 wherein said dose is at least 325 mg/m^2.

42. A formulation of paclitaxel suitable for administration of paclitaxel to a subject in need thereof with a treatment cycle of less than 3 weeks, said formulation comprising paclitaxel in a pharmaceutically acceptable formulation suitable for systemic administration at a dose of at least 135 mg/m^2 over an administration period of no greater than 2 hours.

43. A formulation according to claim 42 wherein said dose is at least 250 mg/m^2.

44. A formulation according to claim 42 wherein said dose is at least 325 mg/m^2.

45. A formulation of paclitaxel suitable for administration of paclitaxel to a subject in need thereof, said formulation comprising paclitaxel in a pharmaceutically acceptable formulation free of cremaphor.

46. A lyophilized formulation of paclitaxel suitable for administration of paclitaxel to a subject in need thereof upon reconstitution.

47. A reconstituted formulation of paclitaxel suitable for administration of paclitaxel to a subject in need thereof, said formulation comprising the lyophilized formulation of claim 41 and water or an aqueous solution.

48. A frozen formulation of paclitaxel suitable for administration of paclitaxel to a subject in need thereof upon thawing.

49. A liquid formulation of paclitaxel comprising water and paclitaxel at a concentration of at least 2.0 mg/ml.

50. A liquid formulation of paclitaxel according to claim 49, wherein said paclitaxel concentration is at least 5.0 mg/ml.

51. A liquid formulation of paclitaxel according to claim 49, wherein said paclitaxel concentration is at least 10.0 mg/ml.

52. A drug formulation suitable for administration of drug to a subject in need thereof by inhalation, said formulation comprising protein microparticles having a size of about 1-10 μm, wherein said protein microparticles comprise drug nanoparticles having a size of about 50-1,000 nm, plus optionally an excipient.

53. A method of making nanoparticles containing an active agent, said method comprising:

a) combining a non-volatile phase, a volatile phase, and a surfactant that spontaneously form a microemulsion, wherein said volatile phase contains said active agent; and

b) removing said volatile phase and thereby obtaining a suspension of solid nanoparticles in said non-volatile phase, wherein said nanoparticles contain

said active agent and have an average diameter of less than 100 nm.

54. A method according to claim 53, wherein said nanoparticles have an average diameter of less than 50 nm.

55. A method according to claim 53, wherein said microemulsion further comprises a cosurfactant.

56. A method according to claim 53, further comprising:

c) removing said surfactant and/or cosurfactant by dialysis, ultrafiltration, or adsorption.

57. A method according to claim 53, further comprising:

c) removing essentially all of the remaining non-volatile phase by freeze-drying, spray-drying, or lyophilization, so as to obtain a dry powder of nanoparticles.

58. A method according to claim 57, further comprising:

d) resuspending said dry powder of nanoparticles in a pharmaceutically acceptable carrier.

59. A method according to claim 58, further comprising:

e) administering said resuspended nanoparticles to a patient.

60. A method according to claim 53, further comprising:

c) filtering said suspension of solid nanoparticles through a filter of sufficiently small pore size so as to sterilize said suspension.

61. A method of making nanoparticles containing an active agent, said method comprising:

a) combining a non-volatile phase and a volatile phase that spontaneously form a microemulsion, wherein said non-volatile phase contains said active agent; and

b) removing said non-volatile phase and thereby obtaining solid nanoparticles in said volatile phase, wherein said nanoparticles contain said active agent and have an average diameter of less than 100 nm.

62. A suspension of nanoparticles made by the method of claim 53.

63. Dry nanoparticles made by the method of claim 57.

64. A suspension of nanoparticles made by the method of claim 58.

65.A suspension of nanoparticles made by the method of claim 61.

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